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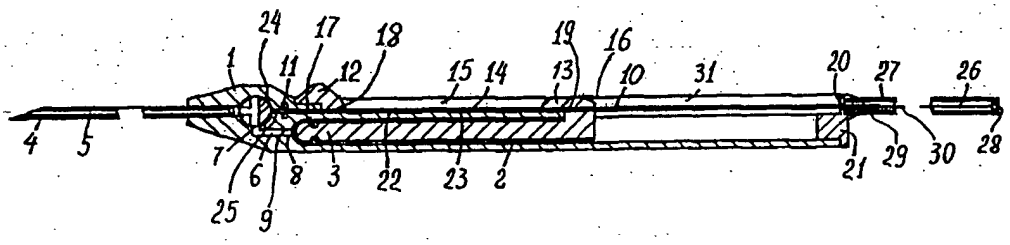

(57) Abstract

Guide wire placement apparatus for guide wire introduction into blood flow, specifically for main blood vessel catheterization according to Seldinger. The apparatus comprises means for indication of puncture needle readings in blood vessels made as a syringe with barrel made integral with the apparatus housing, means for syringe plunger control, guide wire preinstalled within apparatus outside of barrel and in line with the needle, guide wire control zone permitting guide wire control by the same hand that holds the apparatus and controls plunger. The apparatuses can be made with the option of direct control of guide wire by the operator's finger, or equipped with supplementary control member.

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GUIDE WIRE PLACEMENT APPARATUS

FIELD OF THE INVENTION

The invention relates to medical equipment, in particular to devices and appliances for blood vessel catheterization.

BACKGROUND

The devices for guide wire introduction into blood vessels, which is further used as a guide for catheter tube placement to blood vessel, are known.

The device is known from the USA Patent No. 5290244, which comprises base member, mounted between the needle and the syringe. Said base member has lateral entry, through which guide wire enters the needle eye at a shart angle to the needle longitudinal axis. Said lateral entry has rubber sealing, hermetically closing guide wire. Among the device demerits are: relatively high tractive resistance of the guide wire caused by its bending at the point of entry into needle eye. The device is controlled by two hands: one hand holds the syringe, whereas the other controls guide wire. It brings inconveniency into operation and demands a hard-to-reach correlation in actions. Said hindered guide wire progress and two-handed regulation reduce the accuracy of guide wire control. Increased guide wire tractive resistance hampers the indication of guide wire behavior, as it plagues the assessment of possible unpredicted resistance in a blood vessel. It results in the jeopardy of patient's injury not detected by an operator timely.

Two-handed control and increased resistance slow the guide wire progress and enhance catheterization time expenditures.

The USA Patent No. 5290244 is the invention prototype.

The Guide Wire Introducer Assembly is also known from the USA Patent No. 5263938, which comprises guide wire and an orifice for guide wire control by the operator's fingers. This assembly is characterized by the above indicated demerits associated with two-handed control. The device, before use, must be connected to an alternative device with barrel, plunger and needle, thus increasing the catheterization laboriousness.

SUMMARY OF THE INVENTION

The invention objective is upgrading of physician's operation conveniency upon guide wire introduction into patient body,

Another invention objective is reduction of manipulation traumaticity upon guide wire introduction to patient's body.

Another invention objective is labor consumption decrease upon guide wire introduction into patient's body.

Another invention objective is upgrading of guide wire control accuracy.

Another invention objective is improved indication of guide wire behavior in patient's body.

The objectives set are achieved by Guide Wire Placement Apparatus comprising:

- housing with inside placed barrel with inside sliding plunger;

- hollow needle placed on distal end of said housing;

- passage between said needle and said barrel made not in line with said needle and having needle opening and barrel

opening;

- indication volume comprising said barrel, said needle cavity and said passage;

- guide wire preinstalled within apparatus and situated outside of said barrel and in line with said needle;

- sealing means situated at entry of said guide wire into said indication volume proximally of said needle opening of passage, and precluding liquid exit out of said indication volume outside, and air entry into said indication volume;

- guide wire control zone located proximally of said sealing means and permitting said guide wire control by the same hand that holds the apparatus;

Another apparatus, wherein there is an actuator of said plunger situated from the operator-facing apparatus side and permitted for control by the same apparatus-holding hand, and there is an actuator tie-rod connecting said actuator and said plunger.

The apparatus, wherein said control zone permits access to said guide wire for its direct control by the operator's finger.

The apparatus, wherein there are means for said guide wire control.

The apparatus, wherein the surface of said housing wall serves as said base.

The apparatus, wherein said base comprises insert made of material facilitating conductor sliding and precluding scoring, for instance, of steel.

Said apparatus embodiment with guide wire situated outside the barrel permits the guide wire to be in line with needle,

has no bends within the apparatus bounds, thus reducing guide wire tractive resistance. Besides, the apparatus can be totally controlled by one, apparatus-holding hand. As the result operation conveniency rises, traumaticity reduces, time expenditures decrease, guide wire control accuracy rises, and indication of its behavior in patient's body improves.

Apparatus, wherein there are guide means precluding accidental displacement of said guide wire out of said control zone.

Apparatus, wherein there is a base said guide wire is pressed to upon its control.

Apparatus, wherein the surface of said housing wall serves as said base.

Apparatus, wherein said base comprises insert made of material facilitating conductor sliding and precluding scoring, for instance, of steel.

Apparatus, wherein there is a two-positioned controlled cock set in the zone between said sealing means and said needle, which in its first position interconnects the cavities of said passage and needle and locks said guide wire guiding means, while in its second position it connects said guiding means and said needle cavity and locks said passage.

Said apparatus embodiments permit to upgrade guide wire control reliability and operation simplicity.

Apparatus, wherein said passage is made as a channel in said housing.

Apparatus, wherein said passage is made as separate part, for instance, a tube.

Apparatus, wherein said sealing means comprise sealing

member and said guide wire situated between said housing and guide wire.

Apparatus, wherein said sealing member is made as O-ring.

Apparatus, wherein said sealing member is made as calibrated orifice.

Said embodiments of apparatus elements are distinguished by the design simplicity, low price combined with sufficient reliability, and in general, provide cost decrease and the apparatus design simplification.

Apparatus, wherein said guide wire has starting position before operation, when it does not prevent the communication between said barrel and needle, and when hermetic disengagement holds between said indication volume and control zone.

Apparatus, wherein there is a locking means precluding accidental and inappropriate displacement of said guide wire distally out of said starting position.

Apparatus, wherein said two-positioned cock is used as said locking means,

Apparatus, wherein free proximal portion of said guide wire situated proximally of said housing is placed into flexible plastic tube, which is by its distal end connected to said housing and serves as protective jacket of said guide wire.

Apparatus, wherein said flexible plastic tube has closed proximal end face which being placed into said starting position serves as a rest for said guide wire and is a means ensuring precise positioning of said guide wire in its said starting position.

Apparatus, wherein there are means ensuring exact injection of said guide wire into patient's body at a preset depth.

Apparatus, wherein the means for indication of said guide wire reaching the preset depth of injection into patient's body made, for instance, as markers on said guide wire and on immovable section of said apparatus, which coincide at the moment said guide wire reaches present depth of injection into patient's body.

Apparatus, wherein said guide wire comprises distal and proximal portions with smaller diameter at said proximal proximal portion which enters said guide wire control zone at the moment said guide wire reaches preset depth of injection into patient's body, thus resulting into cessation of further advance of said guide wire into patient's body.

Said embodiments permit to ensure precise setting of guide wire starting position and reliable preservation of this position during initial catheterization manipilations, and to ensure the guide wire precise injection into patient's body at a preset depth, which in general upgrades the apparatus control accuracy, reduces potential traumaticity, and facilitates operator's work.

Apparatus, wherein said barrel in its transversal section has non-concentric, for instance, oval shape, allows to approach the apparatus to patient's body upon needle injection, to provide conditions for in line arrangement of needle and guide wire, to upgrade apparatus design in the area of its contact with operator's hand, which in general improves the apparatus ergonomic and functional features.

Apparatus, wherein said guide wire in the position prior to said starting position, for instance, during storage and transportation, has curved distal resilient end, situated freely and distally of the apparatus, and there is a protective means that ensures setting of said guide wire into said starting position without damage to said guide wire curved end by sharp edges of said needle.

Apparatus, wherein said protective means is made as plastic tube, which, prior to setting said guid wire to starting position, is fitted over said needle and has a channel on its distal end, serving as a passage, without any considerable spacing, for said guide wire, whereas its said curved distal resilient end is situated freely and distally of said plastic tube so that said channel is situated distally of said needle, in line with it, and is adapted to straightening of said guide wire curved end and direction of said guide wire into said needle cavity without any contact with its sharp edges upon setting said guide wire into starting position.

Apparatus, wherein said needle is removable and connected to the apparatus only after guide wire is set into said starting position.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention essence and objectives are explained in detail by the drawings where:

Fig. 1 shows general view of the guide wire placement apparatus with direct guide wire control by operator's fingers.

Fig. 2 gives longitudinal 2-2 section of the apparatus

shown in Fig. 1.

Fig. 3 demonstrates transversal 3-3 section of the apparatus shown in Fig. 1.

Fig. 4 demonstrates transversal 4-4 section of the apparatus shown in Fig. 1.

Fig. 5 gives apparatus longitudinal section with guide wire control by a wheel..

DESCRIPTION OF THE INVENTION

Figs. 1, 2 display guide wire placement apparatus comprising housing 1 with inside barrel 2, wherein plunger 3 is located movably; needle 4 with cavity 5 set on distal end of housing 1; passage 6, connecting needle cavity 5 with barrel 2 through needle opening 7 and barrel opening 8 and situated in housing 1 not on line with needle 4; indication volume 9 comprising needle cavity 5, barrel 2 and passage 6; guide wire 10 preinstalled within apparatus and situated outside of barrel 2 in line with needle 4; sealing means at the entry of guide wire 10 to indication volume 9 made as O-ring 11 between housing 1 and guide wire 10 so that O-ring 11 is situated proximally of needle opening 7 and precludes fluid exit out of indication volume 9 outwards and air entry to indication volume 9; plunger 3 actuator 12 movable in guides 31 formed by cut-out 32 in housing 1 and connected by tie-rod 13 with plunger 3; guide wire 10 control zone 14 located proximally of O-ring 11 and actuator 12, whereas actuator 13 tie-rod has cut-out 15, ensuring access to guide wire 10 for its direct control by operator's finger. Actuator 12 and guide wire 10 control zone 14 are situated from the

operator-facing side 16 of the apparatus, thus permitting to control them by the fingers of the apparatus-holding hand of operator. The apparatus has guides made as: channel 17 in housing 1; channels 18 and 19 in actuator 12 and tie-rod 13; channel 20 in cover 21 of housing 1 proximal end; longitudinal groove 22 on housing 1 surface. These guides direct guide wire motion within the apparatus and preclude its accidental displacement out of control zone 14. Base 23 is seen, whereto guide wire 10 is pressed upon its control, and which serves as a surface of housing 1 wall. In an alternative embodiment of Figs. 2, 3 the surface of groove 22 serves as said base. In another alternative embodiment (not shown), an insert made of material, having low friction coefficient in combination with guide wire, for instance, of steel or teflon, serves as said base.

In an alternative embodiment the apparatus has two-positioned cock 24 operator-controlled by handle 33. Cock 24 is set between sealing member (O-ring) 11 and needle 4, and in its first position (see Fig. 2) connects needle cavity 5 with passage 6, and via it, with barrel 2, and locks channel 17 of guide wire 10 guiding means, whereas in its second position (not shown) it connects needle cavity 5 with channel 17 of guiding means, thus locking passage 6.

Fig. 2 shows guide wire 10 in its starting position, prior to operation when its distal end 25 is placed between sealing member 11 and needle opening 7. In this process, cock 24 in said first position locks channel 17, thus blocking accidental displacement of guide wire 10 out of its starting position distally.

The guide wire free proximal section 26 located proximally of housing 1 is placed into flexible plastic tube 27, which by its distal end is fixed in housing cover 21 and serves as guide wire 10 protective jacket. Flexible plastic tube 27 has closed proximal face 28 which serves as a rest for guide wire 10 upon its setting into starting position, and is thus the means of ensuring the guide wire 10 precise setting into its starting position.

In the apparatus of Figs. 1 - 4 guide wire 10 comprises distal 29 and proximal 30 sections with smaller diameter at its proximal section 30 so that this smaller diameter is less than the depth of longitudinal groove 22, wherein guide wire 10 runs. When guide wire 10 reaches reaches the preset depth of injection into patient's body, the guide wire proximal section 30 enters control zone 14 and operator's finger loses functional relationship with guide wire 10, since guide wire does not protrude from groove 22 because of the small diameter at proximal section. As a result, guide wire 10 advance into patient's body stops. In an alternative embodiment (not shown) base 23 has no groove 22 and transition from the guide wire 10 larger diameter on section 29 to the smaller one on section 30 is well perceived by the operator and indicates the achievement of a preset depth of guide wire 10 injection into patient's body. In another alternative embodiment (not shown), some well-noted markers are made on guide wire 10 and, for instance, on flexible plastic tube 27 (which is transparent), that coincide when guide wire 10 reaches the preset depth of injection into patient's body.

As shown in Figs. 3, 4, barrel 2 and plunger 3 are made

oval-shaped, thus reducing the distance between needle 4 and barrel 2 axes. It allows to approach the apparatus and the patient's body upon needle 4 injection, and to upgrade potential reliable targeting of a blood vessel by needle 4. In addition, the apparatus design and ergonomic features are also perfected.

The apparatus alternative embodiment, shown in Figs. 1, 2, envisages the use of removable needle 4, which prior to guide wire 10 setting into starting position is disconnected of the apparatus. In this case the guide wire crooked resilient distal end protrudes freely of the apparatus distal side. It should be taken into account that said crooked resilient distal end is necessary for the guide wire 10 atraumatic leving the needle for vein, and that this distal end must not be kept straightened during the long period of storage and transportation because of possible loss in elasticity and crooked shape. After guide wire 10 is set into starting position, needle 4 is connected to the device. Thus potential damage of guide wire 10 distal end by the needle sharp edges and upon guide wire setting into starting position is precluded.

The apparatus described operates in the following manner.

Holding the apparatus by one hand, operator uses finger of the same hand for acting upon guide wire 10 in control zone 14 and sets guide wire 10 into starting position, moving it proximally until it abutts closed proximal face 28 of flexible plastic tube 27. In this process, cock 24 is in the second position, connecting needle cavity 5 and channel 17 of guide wire 10 guiding means. Further on, acting upon handle 33 by a

finger of the apparatus-holding hand, operator changes cock 24 to first position, connecting needle cavity 5 with barrel 2 through passage 6 and locking guide wire 10 accidental displacement from starting position distally by cock 24. After that, operator inserts needle 2 into housing 1 distal end, injects needle 2 into patient's body and acts on actuator 12 of plunger 3 by a finger of the apparatus-holding hand. In doing this, operator sucks blood into barrel 2. Free blood entry into barrel 2 evidences that needle 4 tip targeted blood vessel. After said targeting operator acting by handle 33 changes cock 24 into the second position, connecting needle cavity 5 with channel 17 of guide wire 10 guiding means, and giving guide wire 10 passage into cavity 5 of needle 4. After that, acting by a finger of the apparatus-holding hand upon guide wire 10 in control zone 14, operator advances guide wire 10 distally into patient's body through needle 4. In doing this and even before this, during blood sucking into barrel 2, sealing member shaped as O-ring precludes blood exit out of indication volume outwards through channel 17, and air entry the same indication volume. When preset
depth of guide wire 10 injection into patient's body is achieved, the guide wire proximal section 30 with diameter smaller than the depth of longitudinal groove 22, wherein guide wire 10 is situated, enters control zone 14. Change in guide wire diameter is per se a sensitive tactile signal for the operator that guide wire 10 has achieved the preset depth. But moreover, in doing this, frictional link between operator's finger and guide wire 10 is lost, resulting in cessation of guide wire advancement into patient's body. Then,

pressing wad to patient's skin in the point of needle 4 injection, operator draws the needle out of patient's body and removes the apparatus, leaving guide wire 10 ready for use as a guide for subsequent catheter tube introduction into patient's body.

Thus, owing to: in-line arrangement of guide wire 10 and needle 4 that reduce guide wire 10 tractive resistance; apparatus single-handed control; means for precise setting of guide wire 10 starting and final position, and prevention of its accidental displacement and damage, and owing to said mutual arrangement of the apparatus parts, upgrading of operation conveniency, reduction of labor consumption, decreased patient's injury and increased guide wire control accuracy in its injection into patient's body are achieved.

Fig. 5 shows the apparatus alternative embodiment, wherein guide wire 10 is situated from the patient-facing side 34 of barrel 2, and there is a guide wire 10 control means made as a wheel 35, located in control zone 14 between sealing member 36 and barrel 2, and having friction engagement with distal portion 29 of guide wire 10, whereas guiding means of guide wire 10 is made as channel 37 in housing 1. Sealing member 36 is made as calibrated orifice. To improve sealing properties, lubrication, in particular, silicon grease, can be applied onto inner working surface of calibrated orifice 36 in an alternative embodiment. The passage, connecting barrel 2 with needle 4 cavity, is made as a separate part, specifically, as tube 38 connected to needle opening 7 and barrel 6 opening 8 situated inside the housing. Tube 38 is located outside the plane of Fig. 5 section and is, therefore, shown schematically

by a dash line. Protective means is made as plastic tube 39, which, before guide wire setting into starting position, is fitted over needle 4 and has channel 40 on its distal end, serving as a passage, without any considerable spacing, for guide wire 10, whereas its curved distal resilient end 41 is situated distally of plastic tube 39. Channel 40 is situated in line with needle 4, which is aided by tight sticking of needle 4 by plastic tube 39 in zone 42. Before operation, the operator acts on wheel 35 by a finger of the apparatus-holding hand, and sets guide wire 10 into starting position. In doing this, plastic tube 39 ensures guide wire 10 entry into needle 4 in straightened form and without any contact with needle tip sharp edges. Then the operator removes plastic tube 39 of the needle, injects needle into the patient's body, and acting by a finger on actuator 12, performs indication of needle 4 targeting a blood vessel, then using wheel 35, injects guide wire 10 into patient's body. When guide wire 10 achieves preset penetration depth, guide wire proximal section 30 with small diameter enters contact zone with wheel 35, which results in the cessation of guide wire 10 friction with wheel 35 and prevents further guide wire 10 advance into patient's body.

When guide wire 10 is placed from the patient-facing side of barrel 2, it permits to approach needle to the patient's body, if various, including cylindrical, sections are used for barrel 2.

As a whole, Fig. 5 apparatus has actually the same benefits as Fig. 2 - 4 embodiments.

CLAIMS

1. Guide wire placement apparatus comprising:

- housing with inside placed barrel with inside sliding plunger;

- hollow needle placed on distal end of said housing;

- passage between said needle and said barrel made not in line with said needle and having needle opening and barrel opening;

- indication volume comprising said barrel, said needle cavity and said passage;

- guide wire preinstalled within apparatus and situated outside of said barrel and in line with said needle;

- sealing means situated at entry of said guide wire into said indication volume proximally of said needle opening of passage, and precluding liquid exit out of said indication volume outside, and air entry into said indication volume;

- guide wire control zone located proximally of said sealing means and permitting said guide wire control by the same hand that holds the apparatus;

2. Apparatus according to claim 1, wherein said guide wire has starting position before operation, when it does not prevent the communication between said barrel and needle, and when hermetic disengagement holds between said indication volume and control zone.

3. Apparatus according to claim 2, wherein there are guide means precluding accidental displacement of said guide wire out of said control zone.

4. Apparatus according to claim 3, wherein there is an

actuator of said plunger situated from the operator-facing apparatus side and permitted for control by the same apparatus-holding hand, and there is an actuator tie-rod connecting said actuator and said plunger.

5. Apparatus according to claim 4, wherein there is a base said guide wire is pressed to upon its control.

6. Apparatus according to claim 5, wherein said control zone permits access to said guide wire for its direct control by the operator's finger.

7. Apparatus according to claim 5, wherein there are means for said guide wire control.

8. Apparatus according to claim 5, wherein the surface of said housing wall serves as said base.

9. Apparatus according to claim 5, wherein said base comprises insert made of material facilitating conductor sliding and precluding scoring, for instance, of steel.

10. Apparatus according to claim 6, wherein said guide wire control zone is situated proximally of said actuator, whereas said actuator tie-rod has a cut-out ensuring said access to guide wire.

11. Apparatus according to claim 7, wherein said guide wire is situated from the patient-facing barrel side, said control means is made as a wheel set between said sealing means and said barrel, whereas said guiding means comprise longitudinal channel in said housing.

12. Apparatus according to claim 3, wherein said passage is made as a channel in said housing.

13. Apparatus according to claim 3, wherein said passage is made as separate part, for instance, a tube.

14. Apparatus according to claim 3, wherein said sealing means comprise sealing member and said guide wire situated between said housing and guide wire.

15. Apparatus according to claim 14, wherein said sealing member is made as O-ring.

16. Apparatus according to claim 14, wherein said sealing member is made as calibrated orifice.

17. Apparatus according to claim 14, wherein there is a two-positioned controlled cock set in the zone between said sealing means and said needle, which in its first position interconnects the cavities of said passage and needle and locks said guide wire guiding means, while in its second position it connects said guiding means and said needle cavity and locks said passage.

18. Apparatus according to claim 3, wherein there is a locking means precluding accidental and inappropriate displacement of said guide wire distally out of said starting position.

19. Apparatus according to claim 17, wherein said two-positioned cock is used as said locking means.

20. Apparatus according to claim 3, wherein free proximal portion of said guide wire situated proximally of said housing is placed into flexible plastic tube, which is by its distal end connected to said housing and serves as protective jacket of said guide wire.

21. Apparatus according to claim 20, wherein said flexible plastic tube has closed proximal end face which being placed into said starting position serves as a rest for said guide wire and is a means ensuring precise positioning of said guide

wire in its said starting position.

22. Apparatus according to claim 1, wherein said barrel in its transversal section has non-concentric, for instance, oval shape.

23. Apparatus according to claim 3, wherein there are means ensuring exact injection of said guide wire into patient's body at a preset depth.

24. Apparatus according to claim 23, wherein the means for indication of said guide wire reaching the preset depth of injection into patient's body made, for instance, as markers on said guide wire and on immovable section of said apparatus, which coincide at the moment said guide wire reaches present depth of injection into patient's body.

25. Apparatus according to claim 23, wherein said guide wire comprises distal and proximal portions with smaller diameter at said proximal proximal portion which enters said guide wire control zone at the moment said guide wire reaches preset depth of injection into patient's body, thus resulting into cessation of further advance of said guide wire into patient's body.

26. Apparatus according to claim 3, wherein said guide wire in the position prior to said starting position, for instance, during storage and transportation, has curved distal resilient end, situated freely and distally of the apparatus, and there is a protective means that ensures setting of said guide wire into said starting position without damage to said guide wire curved end by sharp edges of said needle.

27. Apparatus according to claim 26, wherein said protective means is made as plastic tube, which, prior to

setting said guide wire to starting position, is fitted over said needle and has a channel on its distal end, serving as a passage, without any considerable spacing, for said guide wire, whereas its said curved distal resilient end is situated freely and distally of said plastic tube so that said channel is situated distally of said needle, in line with it, and is adapted to straightening of said guide wire curved end and direction of said guide wire into said needle cavity without any contact with its sharp edges upon setting said guide wire into starting position.

28. Apparatus according to claim 26, wherein said needle is removable and connected to the apparatus only after guide wire is set into said starting position.

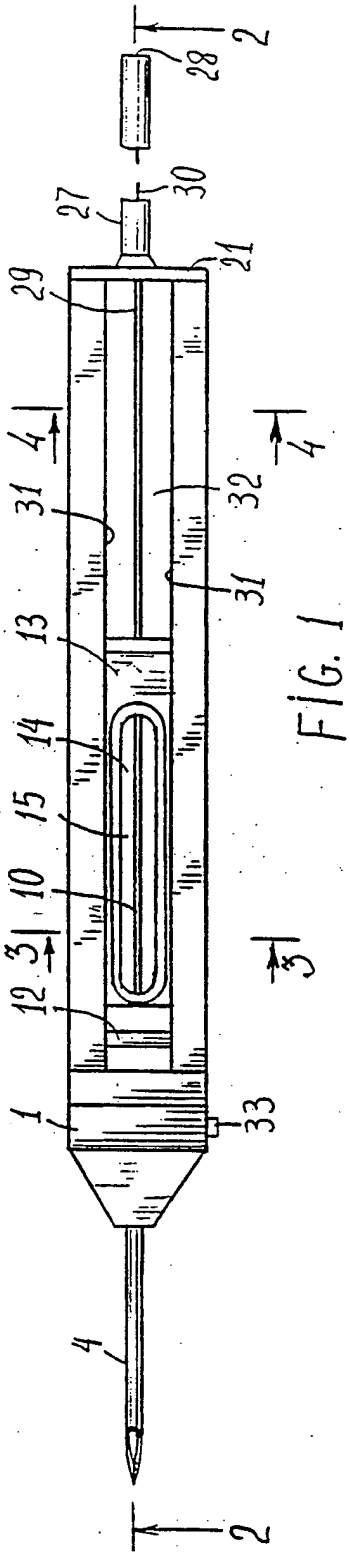

FIG. 1

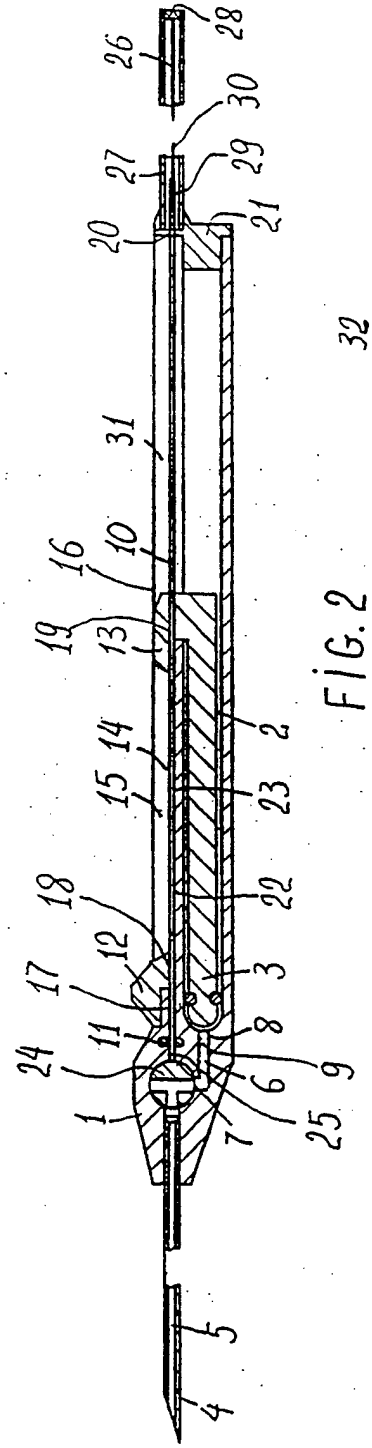

FIG. 2

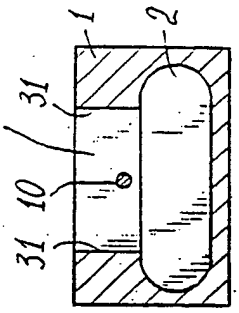

FIG. 4

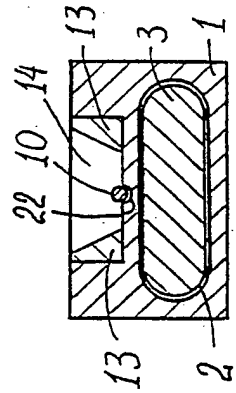

FIG. 3

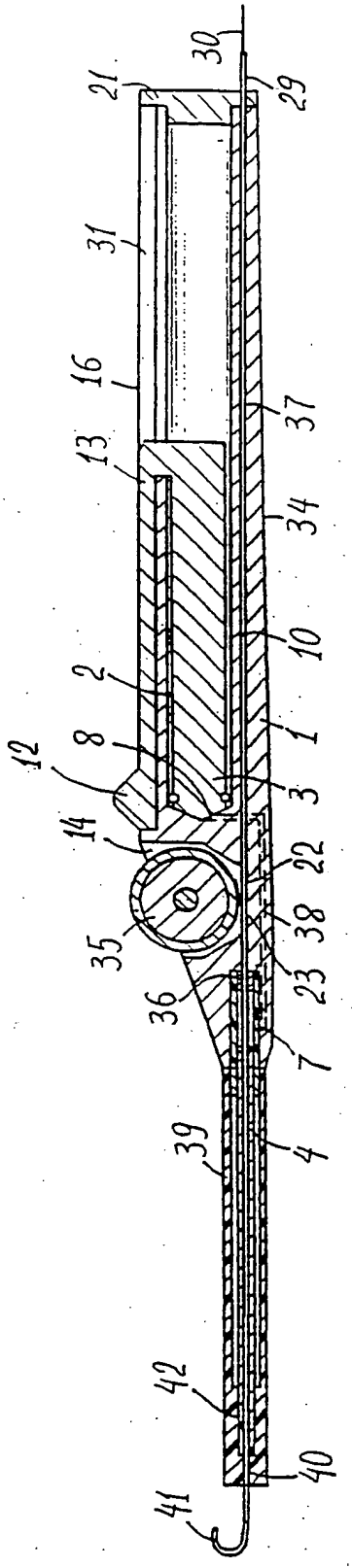

FIG. 5

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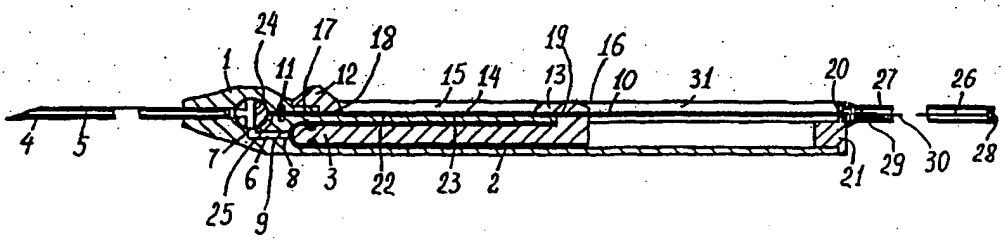

(57) Abstract

This invention is a guide wire placement apparatus for guide wire introduction into blood flow, specifically for main blood vessel catheterization according to Seldinger. The apparatus comprises means for indication of puncture needle readings in blood vessels made as a syringe with barrel (2) made integral with the apparatus housing (1), means for syringe plunger (3) control guide wire pre-installed within apparatus outside of barrel, and in line with the needle (4), guide wire control zone permitting guide wire control by the same hand that holds the apparatus and controls plunger. The apparatus can be made with the option of direct control of guide wire by the operator's finger or equipped with supplementary control member.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00357

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 5/178
US CL :604/158
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/158, 159, 164, 181, 187, 218

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E	US 5,749,371 A (ZADINI ET AL.) 12 MAY 1998, FIG. 1.	1-3, 12-14, 18, 23
A	US 5,527,291 A (ZADINI ET AL.) 18 JUNE 1996, ABSTRACT.	1-28
A	US 5,325,746 A (ANDERSON) 05 JULY 1994, ABSTRACT.	1-28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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